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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,240	10/21/2005	Zheng Xin Dong	119P/PCT2/US	5791

7590 09/03/2009

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,240	DONG ET AL.	
	Examiner	Art Unit	
	ANDREW D. KOSAR	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) *18 and 21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/18/05,11/10/06,12/9/08,7/24/09, 8/4/09.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and the compound of Example 22, in the reply filed on March 3, 2009 is acknowledged. The traversal is on the ground(s) that Applicant asserts Fuselier does not teach a compound within the scope of claim 1 and therefore unity of invention exists. Applicant further argues that Schally (WO 97/19954 A1) does not read on the claims, as it does not have a Doc or Aepa. This is not found persuasive because as drafted, the claims do not require that one select Aepa or Doc, or the succinyl derivative for the linker. As drafted the claim clearly indicates that "each of B^1, … *is, independently for each occurrence*," and this does not specifically require that one must select any specific group at any position. For example, there is nothing that prevents each of B^{1-4} from being $(\text{amino acid})_p$ where p is zero. In this, the resultant compound is effectively X-Z. There is no requirement that any single position must be Aepa, Doc or the C(O)-A1...A5-C(O) moiety. As such, the carbamate linkage compound of Fuselier reads on the claim, as R_1-C(O) is the 'cytotoxic' group, B^1 is $(\text{amino acid})_p$ where p=0, B^{2-4} is each $(\text{amino acid})_p$ where p= 1, 2 and 2, respectively, and Z is the somatostatin. Nothing precludes this interpretation, as there is no requirement that one must always have one of the recited Aepa, Doc or C(O)-A1...A5-C(O) moiety as part of the linker. Further, with regards to Schally, again, the claims as drafted require that $(\text{Doc})_m$ and $(\text{Aepa})_n$ are not zero, however this merely limits the subset from which one can select the B^{1-4} moieties, and it is properly interpreted that one need not select the C(O)-A1...A5-C(O) moiety and $(\text{amino acid})_p$ with p=0 for the remainder of the residues. Applicant's arguments appear to indicate that at least one of B^{1-4} must be the C(O)-A1...A5-C(O) moiety and in the proviso at least one other

must be Aepa or Doc, however the claim is not drafted in this manner. Again, as discussed above, the claim allows for independent selection of any of the variables for B, and makes no requirement that the compound must have the C(O)-A1...A5-C(O) moiety. Thus, Applicant's arguments are not persuasive.

Furthermore, assuming *arguendo* that the claims require the C(O)-A1...A5-C(O) moiety, FISCHER (WO 00/01417 A1) relied upon below under §102(b), teaches the compound bohemine-βAla-Suc-βAla-RQIKIWQNRRMKWKK-OH, where the peptide is a nuclear localization sequence, which satisfies the requirement for the ligand of a biological receptor, an analog or derivative thereof. Bohemine is a CDK inhibitor and βAla-Suc-βAla is the linker where $B^{1 \text{ and } 3}$ are β-Ala, B^2 is Suc and B^4 is $(\text{amino acid})_0$. Thus, even if Applicant maintains that the examiner has not provided a *prima facie* case previously, Fischer shows additional evidence of a lack of unity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 18 and 21-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 3, 2009.

Applicant's elected species was found to be free of the prior art. The search was extended to the compounds of claims 14-17, which also were found to be free of the prior art.

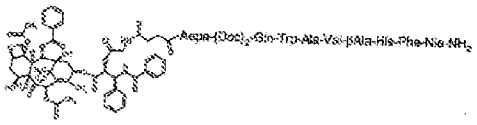
The search was extended to the additional species within the generic claim, as set forth below. Applicant is reminded that the search is not extended unnecessarily to cover all nonelected species.

Allowable Subject Matter

Claims 14-17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph and the objections to the claims, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Specification

The disclosure is objected to because of the following informalities: The specification recites sequences without sequence identifiers, e.g. page 10, the compound:



Appropriate correction is required.

Please note, the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claims 2-15 are objected to because of the following informalities:

Claims 2 and 3 have an extra period at the end of the claim.

Claims 2-15 are dependent claims and should recite "The compound…" rather than "A compound".

Claim 14 recites sequences that require sequence identifiers (SEQ ID NO). For example, the 3rd, 5th and 7th compounds on page 9 (claim set of 6/3/09), as well as al compounds that have four or more specifically defined amino acids which are not D-amino acids and are not branched sequences (e.g. 4th and 5th compounds on page 10 of the claim set of 6/3/09).

Appropriate correction is required.

Claims 14-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 14-17 are broader in scope than the independent claim, as the independent claim does not allow for additional elements afforded by the term "comprises" being drawn to A compound according to formula (I).

Sequence Compliance

Applicant is advised that the application is not in compliance with 37 CFR §§ 1.821-1.825.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR §§ 1.821- 1.825) in order to effect a complete response to this office action.

Specifically, the claims and specification (e.g. claim 14 and spec page 10), described above, recite sequences without sequence identifiers.

> 37 CFR § 1.821 (a) states,
> "Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. "Specifically defined" means those amino acids other than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2."
>
> (a)(2) states,

"*Amino acids*: Amino acids are those L-amino acids commonly found in naturally occurring proteins and are listed in WIPO Standard ST.25 (1998), Appendix 2, Table 3. Those amino acid sequences containing D-amino acids are not intended to be embraced by this definition. Any amino acid sequence that contains post-translationally modified amino acids may be described as the amino acid sequence that is initially translated using the symbols shown in WIPO Standard ST.25 (1998), Appendix 2, Table 3 with the modified positions; e.g., hydroxylations or glycosylations, being described as set forth in WIPO Standard ST.25 (1998), Appendix 2, Table 4, but these modifications shall not be shown explicitly in the amino acid sequence. Any peptide or protein that can be expressed as a sequence using the symbols in WIPO Standard ST.25 (1998), Appendix 2, Table 3 in conjunction with a description in the Feature section to describe, for example, modified linkages, cross links and end caps, non-peptidyl bonds, etc., is embraced by this definition."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 13 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Factors to be considered in making the determination as to whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing include: (a) Actual reduction to practice; (b) Disclosure of drawings or structural chemical formulas; (c) Sufficient relevant identifying characteristics such as: (i) Complete structure, (ii) Partial structure, (iii) Physical and/or chemical properties or (iv) Functional characteristics when coupled with a known or disclosed correlation between function and

structure; (d) Method of making the claimed invention; (e) Level of skill and knowledge in the art and (f) Predictability in the art. While all of these factors are considered, a sufficient number for a *prima facie* case are discussed below.

For Applicant's clarification, the rejection is set forth with regards to the moiety "Z".

The claims are drafted where Z is the ligand of a biological receptor, an analog thereof, or a derivative of said ligand or of said analog. The claims require the *a priori* knowledge of the biological receptor intended, where Applicant has only exemplified LHRH, bombesin and somatostatin. While analogs and derivatives of these ligands may be known to the artisan, the claims are drafted to analogs and derivatives of the ligand for any receptor, where the receptor is undefined, as well as being drawn to derivatives of the analogs. The specification provides no structure- partial or complete- of the derivative of an analog of a ligand for an undefined biological receptor. The specification provides no guidance as to how one would ascertain or identify this analog or derivative of an unidentified ligand, and while the artisan may understand the concept of targeting ligands, the *a priori* knowledge of what is a derivative or analog of the ligand- which has not been identified, or the identity of the derivative of the analog of the unidentified ligand is beyond the skill and knowledge of those in the art, as it is understood in the peptide art that one cannot ascertain the effect of amino acid substitution on function, and thus by extension, one would not be able to reasonably predict that a peptide would target a biological receptor without undue experimentation.

Although the claims may recite some functional characteristics (ligand of a biological receptor), the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically

disclosed in the examples in the specification. Moreover, the specification lacks a sufficient variety of species to reflect this variance in the genus. While having written description of LHRH, bombesin and somatostatin and compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims for the variable Z.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that each B^{1-4} is independently for each occurrence $(Doc)_m$, $(Aepa)_n$, $(amino\ acid)_p$ or $(C(O)\text{-}A1...A5\text{-}C(O))_s$, however it is unclear how one can independently select DOC, Aepa, etc., when s=1, as there is no requirement in the claim that one must select C(O)-A1...A5-C(O). As such, the claim sets up contradictory requirements, and is indefinite. One could set s=5, and yet not 'select' $(C(O)\text{-}A1...A5\text{-}C(O))_5$ for any of B^{1-4}. Furthermore, in light of

Applicant's remarks regarding the lack of unity, it is unclear whether any one of B^{1-4} must be present and, if so, must be C(O)-A1...A5-C(O) or when X is doxorubicin one of m and n may not be zero, however, again, such requirement does not require selection of Aepa or Doc. In contrast, see claim 2, which positively recites that X is a cytotoxic moiety, providing clarification that one may not select cytostatic agent, or the proviso that when X is paclitaxel then B^1 is $(\text{amino acid})_{1 \text{ or } 2}$, which specifically require the selection of those entities. Thus, the claims are indefinite.

Additionally, claim 1 recites that R^1 and R^2 "together can form" C_{3-30} cycloalkyl, C_{3-30} heterocycle or C_{3-30} aryl, however it is unclear how one forms this without the 'carbon to which they are attached' if they are 'taken together', as one could not form a ring with two side chains without utilizing the central carbon.

Claims 14-17 lack clear antecedent basis, as they are drawn generally to compounds comprising the recited formulae, however this is broader than claim 1 which is "A compound according to formula (I)". This, the claims lack antecedent basis, in that the independent claim does not allow for additional elements to be present.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by FISCHER (WO 00/01417 A1).

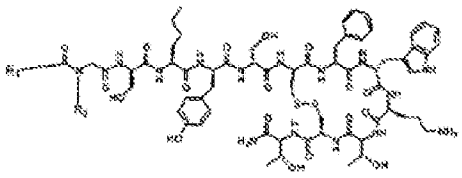
Fischer teaches the compound: bohemine-βAla-Suc-βAla-RQIKIWQNRRMKWKK-OH (e.g. claim 33), where the peptide is a nuclear localization sequence, which satisfies the

requirement for the ligand of a biological receptor, an analog or derivative thereof. Bohemine is a CDK inhibitor and βAla-Suc-βAla is the linker where $B^{1 \text{ and } 3}$ are β-Ala, B^2 is Suc and B^4 is $(\text{amino acid})_0$. Fischer teaches that the compounds are useful for treating cancer and are formulated as pharmaceutical compositions (e.g. page 12).

Claims 1-4, 9-13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHALLY (WO 97/19954 A1; IDS 11/18/05, reference O).

Schally teaches doxorubicin and analogs of doxorubicin coupled through a diacid linker, e.g. glutarate or succinate, to peptide hormones analogs of LHRH, bombesin and somatostatin (e.g. Abstract, pages 12 and 13). As discussed above, nothing precludes selection of the non-Doc/Aepa moieties, e.g. all $(\text{amino acid})_p$ where p is zero. Schally teaches the compounds as pharmaceutical compositions (e.g. claim 32).

Claims 1-4, 10, 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by FUSELIER (IDS 11/18/05, reference U).

Fuselier teaches the compound:  (Table 1). As described above, R_1-C(O) is the 'cytotoxic' group, B^1 is $(\text{amino acid})_p$ where p=0, $B^{2\text{-}4}$ is each $(\text{amino acid})_p$ where p= 1, 2 and 2, respectively, and Z is the somatostatin. The analogs were inclubated in 0.1 M PBS or fresh rat serum, and neither is precluded from use as a pharmaceutical carrier. Furthermore, the compounds are clearly indicated as intended for use as pharmaceuticals in treating cancer, and thus necessarily would be found to be in a pharmaceutical composition.

Claims 1, 2, 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by ARAP (WP 02/20722 A2).

Arap teaches conjugates of delivery peptides to anti-angiogenic agents, e.g. paclitaxel, and pharmaceutical compositions thereof (e.g. claims 63 and 75).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **1-13 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over FISCHER, above, in view of SCHALLY, above.

The teachings of Schally and Fischer are above. Schally additionally teaches that the linker is a dicarboxylic acid spacer "like glutaric acid" (page 7). One carboxylic acid of the spacer forms an ester with the DOX/DOX derivative, and the other forms an amide with the delivery peptide.

Fischer teaches that "Using these methods, the skilled person will be capable of preparing a wide variety of drug-carrier conjugates utilizing a variety of linker moieties. As exemplified below, an appropriate group may be selected for attachment to the carrier moiety and if desired a linker joined to the drug or carrier moiety, or both prior to their coupling." (page 12).

Fischer additionally teaches that the drug is preferably a cytotoxic/neoplastic agent (e.g. spanning pages 4 and 5), including doxorubicin, paclitaxel, camptothecin, etc.

Fischer teaches that indirect linkage, through a linker is preferred (e.g. page 6) and that suitable linkers including bi- and multi-functional alkyl, aryl, etc. (page 6-7), including amino acids/short peptides and that the linker and the drug/delivery peptide will form a bond through a covalent bond using amides, carboxylates, etc.

The difference between the instant claims and the teachings of Fischer is that while Fischer teaches one could use any drug with any linker and any targeting moiety, embodying one particular species, as described above under § 102(b), Fischer does not specifically teach paclitaxel, doxorubicin or other cytotoxic agents specifically attached to the delivery peptide.

It would have been obvious to have formed any combination of cytotoxic agent, linker and delivery agent, as it is taught by Fischer that one could do so. Furthermore, the linker of Fischer is a dicarboxylic acid linker, and one would have been motivated to have used it in the compound of Schally, in that it is a functional equivalent- both being described in the art as linkers being used to link cytotoxic agents to a delivery peptide. Additionally, one would have been motivated to have used any targeting sequence, including the LHRH, somatostatin and bombesin analogs, to deliver the chemotherapeutic to the desired cells, as they are all described as targeting sequences used to deliver their cargo- the chemotherapeutic- to the desired target. One would reasonably expect the compounds to deliver their cargo to the intended target, as the delivery peptides are well understood to target the respective receptors.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12

USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2006/0153775, US 2006/0034773, US 2004/0018974, US 2002/0147136, US 7,109,167, US 6,472,507, US 7,238,665, US 7,135,574, US 7,420,030, US 7,211,240, and WO 2003/074005 A2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654